DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Public Health Service

Memorandum

Date · AUG 18 1999

From Senior Regulatory Scientist, Regulatory Branch, Division of Programs & Enforcement Policy (DPEP), Office of Special Nutritionals, HFS-456

Subject 75-day Premarket Notification for New Dietary Ingredient

To Dockets Management Branch, HFA-305

New Dietary Ingredients:	*Ganoderma lucidum* Spore Powder
Firm:	GloboAsia LLC
Date Received by FDA:	June 28, 1999
90-day Date:	September 25, 1999

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In accordance with the requirements of section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification for the aforementioned new dietary ingredient should be placed on public display in docket number 953-03 16 after September 25, 1999.

Robert J. Moore, Ph.D.

955-0316

RPT 52

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

AUG 1 8 1999

Nancy Kan, Ph.D.
Senior Regulatory Scientist
GloboAsia, LLC
7250 Parkway Drive
Suite 340
Hanover, Maryland 21076

Dear Dr. Kan:

This is to notify you that your submission pursuant to section 4 13(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) dated May 20, 1999, concerning the marketing of a substance that you assert is a new dietary ingredient (i.e., *Ganoderma Lucidum* Spore Powder) was received by the Food and Drug Administration (FDA) on June 28, 1999. Your submission will be kept confidential for 90 days from the date of receipt, and after September 25, 1999, your submission will be placed on public display at Dockets Management Branch (Docket No. 953-03 16). Commercial and confidential information in the notification will not be made available to the public.

Please contact us if you have questions concerning this matter.

Sincerely,

Robert J. Moore, Ph.D.
Senior Regulatory Scientist
Division of Programs and Enforcement Policy
Office of Special Nutritionals

GloboAsia LLC
美國環亞藥業有限公司
www.globoasia.com
72 Hanover Parkway Drive Suite 210 340
Maryland
Phone: 410-712-0600 Fax: 410-712-9547

June 23, 1999

Robert J. Moore, Ph.D.
Senior Regulatory Scientist
Division of Programs and Enforcement Policy
Office of Special Nutritionals (HFS-456)
Center for Food safety and Applied Nutrition
U.S. Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

RE: 75-day Premarket Notification for New Dietary Ingredient

Dear Dr. Moore,

As the authorized U.S. agent and on behalf of our client Green Power Health Products International Company, Ltd. ("Green Power"), notice is hereby given pursuant to the requirements of Section 413 (a)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 350B) of the intent of Green Power to market a new dietary ingredient, Ganoderma Lucidum Spore Powder, in the U.S. The brand name for the product is Enhanvol Ganoderma Sporo-Pollon (100%). Accordingly, an original and two copies of this notification and related product information are submitted for your reference.

The new dietary ingredient will be sold in 300 mg capsules. The recommended dose is taking orally l-2 capsules each time, up to 3 times a day.

Five toxicity tests using this new dietary ingredient were included in this submission to support that this ingredient is safe to use. In the acute toxicity test, 40 mice were giving an oral dose of Spore Powder between 2.15 and 21.5 g/kg body weight. All animal survived and no toxic reactions were observed over one week. The estimated LD_{50} is larger than 21.5 g/kg and this compound is not considered toxic according to the acute toxicology classifications. This high dose of 21.5 g/kg is more than 800 times the recommended maximum daily oral dose (1.8 g) for a person of 70 kg body weight.

The accumulative toxicity test in 60 mice given daily dose for over 21 days showed that no significant difference in the changes of body weight between the control and the treatment groups. Furthermore, no abnormalities of the internal organs were observed for both groups. It is concluded that this dietary ingredient did not have any accumulative toxicity in animals.

Other toxicity studies indicated that this dietary ingredient did not induce mutations in the mouse micronucleus test and in the Ames test. It did not cause abnormalities of mouse sperms.

Based on the information submitted, we have concluded that this dietary ingredient, Ganoderma Lucidum Spore Powder, will reasonably be expected to be safe under the recommended Directions For Use.

Please direct all correspondence to me and fell free to call me at (410) 712-0609 if you have any question regarding this matter.

Sincerely yours,

Nancy Kan, Ph.D.
Senior Regulatory Scientist
GloboAsia LLC

Enclosures

cc. Green Power Health Products International Company, Ltd.